

UNITED STATES DISTRICT COURT
DISTRICT OF MAINE

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| IMS HEALTH CORP., ET AL., |) | |
| |) | |
| Plaintiffs, |) | |
| v. |) | CV-07-127-B-W |
| |) | |
| G. STEVEN ROWE, |) | |
| ATTORNEY GENERAL OF THE |) | |
| STATE OF MAINE, |) | |
| |) | |
| Defendant. |) | |

ORDER ON MOTION TO AMEND JUDGMENT

The Court amends its preliminary injunction to allow the state of Maine agencies to engage in the non-enforcement activities the amendments to the Prescription Privacy Law contemplate.

I. BACKGROUND

On December 21, 2007, the Court issued an Order granting the Plaintiffs' motion for preliminary injunction against certain provisions in L.D. 4, "An Act to Amend the Prescription Privacy Law." *Order on Pls.' Mot. for Prelim. Inj.* (Docket # 71) (*Order*). On December 28, 2007, the Attorney General moved under Rule 59(e) for an amended judgment, asking that the Court lift the injunction as to particular statutory provisions. *Def.'s Mot. to Amend J.* (Docket # 72) (*Def.'s Mot.*). The Plaintiffs objected, *Pls.' Resp. in Opp'n to Mot. to Amend J.* (Docket # 76) (*Pls.' Resp.*), and the Attorney General replied. *Def.'s Mem. in Reply to Pls.' Opp'n* (Docket # 80) (*Def.'s Reply*).

II. THE PARTIES' POSITIONS

A. The Attorney General's Enforcement Only Position

The Attorney General stresses that he is not contesting the merits of the Order, which he intends to appeal, and he is not contesting the portion of the Order that enjoins the Law's enforcement provisions; rather, he contends that the Order went further than necessary by enjoining governmental activities which do not relate to the enforcement of the provisions of the Law that the Court concluded were unconstitutional. He asks that the Court amend the injunction to exclude the following:

1. 22 M.R.S.A. § 1711-E(4) – Confidentiality protection procedures, so long as the application process includes notice of the Court's Order enjoining enforcement of § 1711-E(2-A);
2. 22 M.R.S.A. § 1711-E(5) – Rules – Department of Health and Human Services (DHHS), so long as it does not involve enforcement of § 1711-E(2-A);
3. 22 M.R.S.A. § 8704(4) – Rulemaking – Maine Health Data Organization (MHDO), so long as it does not involve enforcement of § 1711-E(2-A); and,
4. 22 M.R.S.A. § 8713 – regarding the establishment of procedures for the Maine Health Data Organization to accept filings from certain health care providers.

Section 1711-E(4) requires the applicable boards of licensure for prescribers, as part of their application process for licensure and relicensure, to include notices that the prescribers' prescription drug histories are used for marketing purposes and to inform them that they may opt-out by completing a notice to that effect. The licensing boards are then required on a monthly basis to supply lists of opt-out prescribers to the MHDO. On each October 1, beginning in 2007, DHHS assesses annual fees against pharmaceutical companies, 80% of which covers the costs of the MHDO and 20% of which is retained by DHHS. Section 8713 allows the MHDO to

establish procedures to accept prescriber filings from the licensing boards; sections 1711-E(5) and 8704(4) authorize the MHDO and DHHS to promulgate rules to implement the Law.

The Attorney General's main point is that while the narrowest judicial remedy would be to prohibit enforcement of the statute's unconstitutional provisions, the Order extends to "certain non-enforcement activities even though these activities do not affect the constitutional rights of Plaintiffs." *Def.'s Mot.* at 2. The Attorney General argues:

These non-enforcement activities include allowing certain State agencies to continue to permit prescribers to register and provide information to them so as to be listed as having opted out of the disclosure of their prescribing activity, to compile for public information the identities of those prescribers, and to collect fees due by statute from drug manufacturers upon which the State has relied to cover the costs (some of which already has been incurred) of implementing and operating the Law, including the system for prescriber registration, the system for transfer of that registration information among agencies, and the system for compiling and disclosing the identity of those prescribers, if the State desires to proceed in that manner.

Id. The Attorney General continues, arguing that "[t]he Order provides relief beyond that sought by Plaintiffs and affects entities which are not parties to this lawsuit." *Def.'s Reply* at 2.

B. The Plaintiffs' Severability Analysis

The Plaintiffs respond that a severability analysis is appropriate here. Quoting *Town of Windham v. LaPointe*, the Plaintiffs contend that the "legislative provisions are so related in substance and object that it is impossible to determine that the legislation would have been enacted except as an entirety, if one portion offends the Constitution, the whole must fail." *Pls.' Resp.* at 5 n.9; (quoting *Town of Windham*, 308 A.2d 286, 292 (Me. 1973)); *see* 1 M.R.S.A. § 71(8).

III. DISCUSSION

A. Severability

“Severability is of course a matter of state law.”¹ *Leavitt v. Jane L.*, 518 U.S. 137, 139 (1996); *Rhode Island Med. Soc’y v. Whitehouse*, 239 F.3d 104, 106 (1st Cir. 2001). The absence of a severability clause does not alter the legal analysis. “Rules of statutory . . . construction . . . designed to effect legislative intent, do recognize that partial unconstitutionality of a statute . . . does not necessarily result in tainting the whole legislation, even in the absence of a severability clause.” *Town of Windham*, 308 A.2d at 292. Maine law mandates that the “provisions of the statutes are severable.” 1 M.R.S.A. § 71(8). To determine severability, the Court “considers the legislative purpose or purposes of the statute under consideration” *Opinion of the Justices*, 2004 ME 54, ¶ 23, 850 A.2d 1145, 1152. “When the provisions of a statute ‘are so related in substance and object that it is impossible to determine that the legislation would have been enacted except as an entirety, if one portion offends the Constitution, the whole must fall.’” *Id.* at ¶ 25, 850 A.2d 1152 (quoting *Windham*, 308 A.2d at 292).

Here, the Law expressly delineates its intent. 22 M.R.S.A. § 1711-E(1-A)(A-F), (1-B)(A-C). The Maine Legislature made express findings of the state’s interests in enacting the Law: “to improve the public health, to limit annual increases in the cost of health care, and to protect the privacy of patients and prescribers in the health care system of this State.” *Id.* § 1711-E(1-A). The Legislature also delineated the Law’s purposes: “to protect patient confidentiality” and to “protect personal privacy rights.” *Id.* § 1711-E(1-B)(A)(B). To the extent that the Law’s purposes concern patient privacy, the Law is unaffected by the injunction, since § 2 of the Law was not enjoined.

¹ In this context, severability is not dissimilar from the Court’s obligation “when confronting a constitutional flaw in a statute . . . to limit the solution to the problem.” *Ayotte v. Planned Parenthood of Northern New England*, 546 U.S. 320, 328 (2006). The preference is “to enjoin only the unconstitutional applications of a statute while leaving other applications in force or to sever its problematic portions while leaving the remainder intact.” *Id.* at 328-29 (citations omitted).

The remaining purposes are: (1) to “protect prescribers’ expectations of privacy”; (2) to free prescribers “from pressure to prescribe based on comparisons among them and their peers and aiding them in making health care decisions based on the best interests of the patient and on medical and scientific evidence about prescription drugs and health care treatments”; (3) to “decrease the influence of drug representatives”; (4) to “build patient and prescriber confidence in the health care system”; (5) to “end the use of prescriber comparisons for purposes related to manufacturer profitability”; and, (6) to “decrease unnecessary marketing costs.” *Id.* § 1711-E(1-B)(A)(B). The Attorney General urges the Court to allow the state to collect the names of opt-out prescribers, to “compile for public information the identity of those prescribers,” and to “collect fees . . . to cover the costs . . . of implementing and operating the Law,” including new systems necessary to effectuate the Law’s provisions. *Def.’s Mot.* at 2.

If the enforcement provisions of the Law are enjoined, how would the remaining provisions enhance the legislative purposes? Collecting the names of prescribers who would opt-out, if allowed to do so, could assist the Legislature to make its crucial public policy judgments, including whether it has identified an issue that resonates with prescribers. If the number of opt-out prescribers is small, the Legislature could well conclude that it has created a solution in search of a problem. On the other hand, if the number is large, the Legislature could be encouraged to consider alternatives that would pass constitutional muster. The Attorney General qualified its request by emphasizing that it would notify prescribers of the Court’s Order enjoining enforcement. So long as the Attorney General does not propose enforcement rulemaking, there is no reason to enjoin either MHDO or DHHS from promulgating regulations that would allow for the collection of prescriber information under 22 M.R.S.A. §§ 1711-E(5) and 8704(4).

Finally, the Attorney General requests that the injunction be amended to allow the state to collect the fees authorized by § 1711-E(4)(C). The Attorney General makes the point that in collecting opt-out prescriber information, the state has incurred and will continue to incur costs and that the statute authorizes the collection of fees from drug manufacturers to cover these costs. *Def.'s Mot.* at 2. The Attorney General states that the collection of fees from pharmaceutical companies to establish a system for prescriber registration, for the transfer of registration information among agencies, and for the compilation and disclosure of the identity of those prescribers would not infringe the constitutional concerns that underpin the Court's injunction. *Id.* The Court agrees. If the state wished to survey prescribers who would opt out, if they could, and to establish a system for collecting and collating that information, the imposition of a fee against pharmaceutical companies to fund the survey would pose no issues of constitutional dimension.

B. Parties Bound by the Temporary Injunction

The Attorney General also raises an alternative basis for challenging the scope of the injunction: whether it went too far in reaching state agencies which were not parties to the case. This is a complex question that the Court does not reach, because it has resolved the matter based on a severability analysis.

C. Other Injunction Considerations

Even if the Law had come into effect on January 1, 2008, the state of Maine would not have been able to immediately enforce it, because, among other things, the Law contemplates the promulgation of rules from two state agencies and the gradual collection of opt-out prescriber information compiled through a staggered licensing and relicensing process. It is true that if the state proceeds with the collection of opt-out prescriber information and establishes systems to

share and collate the information, the state could finalize those aspects of the Law that require time to complete while this case is being resolved on appeal. By allowing the state to collect opt-out prescriber information and to establish systems that would make the Law enforceable, the state will be in a much better position to immediately enforce the Law's requirements against the Plaintiffs, if this Court's injunction is not affirmed.

This ordinarily would be of no concern to the Court. However, here, one of the Court's proper considerations in issuing the Order was the impact on the Plaintiffs:

The impact on the Plaintiffs is to require the expenditure of considerable sums of money to alter computer and software applications, to find and delete the subset of opt-out data and to maintain the accuracy of a changing opt-out list, to renegotiate their contracts with their drug company customers to prevent the drug companies' improper use of the opt-out data, and to assume a policing role over their customers to attempt to assure their compliance with a Law that does not apply to them.

Order at 40. How the Plaintiffs would respond to the ongoing collection of opt-out prescriber information, whether they would expend time and resources to comply with the portions of the law that the Court has declared unconstitutional, and whether the state would act precipitously against the Plaintiffs if the Law is ultimately deemed constitutional remain matters of speculation.

IV. CONCLUSION

The Court GRANTS the Defendant's Motion to Amend Judgment (Docket # 73). The Court's Amended Order on Plaintiffs' Motion for Preliminary Injunction is further amended as follows:

The Court grants the Plaintiffs' motion for a preliminary injunction as to the following statutory provisions:

1. 22 M.R.S.A. § 1711-E(2-A), regarding the confidentiality of prescription drug information that identifies the prescriber;
2. 22 M.R.S.A. § 1711-E(3), regarding enforcement, but only to the extent it provides for enforcement of provisions other than § 1711-E(2);
3. 22 M.R.S.A. § 1711-E(5), only to the extent it requires DHHS to promulgate rules enforcing § 1711-E(2-A); and,
4. 22 M.R.S.A. § 8704(4), only to the extent it requires MHDO to promulgate rules enforcing § 1711-E(2-A).

More specifically, the Court amends its Order to clarify that the following provisions remain unaffected by the Court's injunction:

1. 22 M.R.S.A. § 1711-E(4), so long as the application process includes notice of the Court's Order enjoining enforcement of § 1711-E(2-A);
2. 22 M.R.S.A. § 1711-E(5), regarding DHHS rulemaking authority other than rulemaking to enforce § 1711-E(2-A);
3. 22 M.R.S.A. § 8704(4), regarding MHDO rulemaking authority other than rulemaking to enforce § 1711-E(2-A); and,
4. 22 M.R.S.A. § 8713.

SO ORDERED.

/s/ John A. Woodcock, Jr.
JOHN A. WOODCOCK, JR.
UNITED STATES DISTRICT JUDGE

Dated this 15th day of February, 2008